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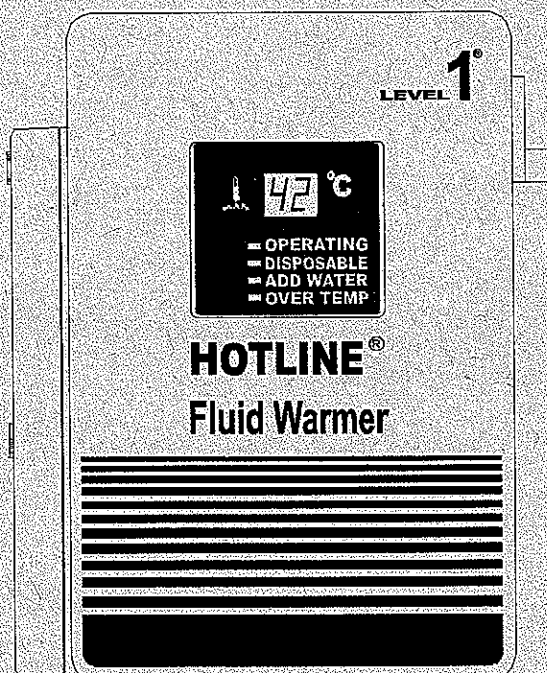
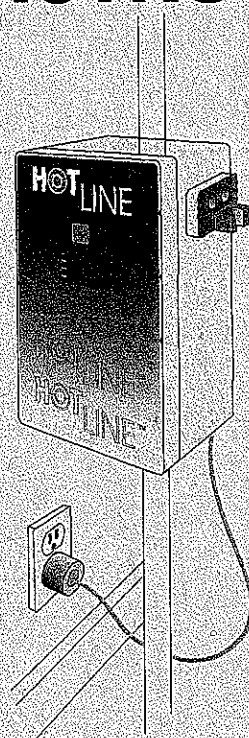
HL-90 115V

HL-90 230V

HOTLINE®

Fluid Warmer

INSTRUCTIONS FOR USE



LEVEL 1®

Level 1, Inc.
160 Weymouth St.
Rockland, MA 02370 USA



1-800-553-8351
1-781-878-8011

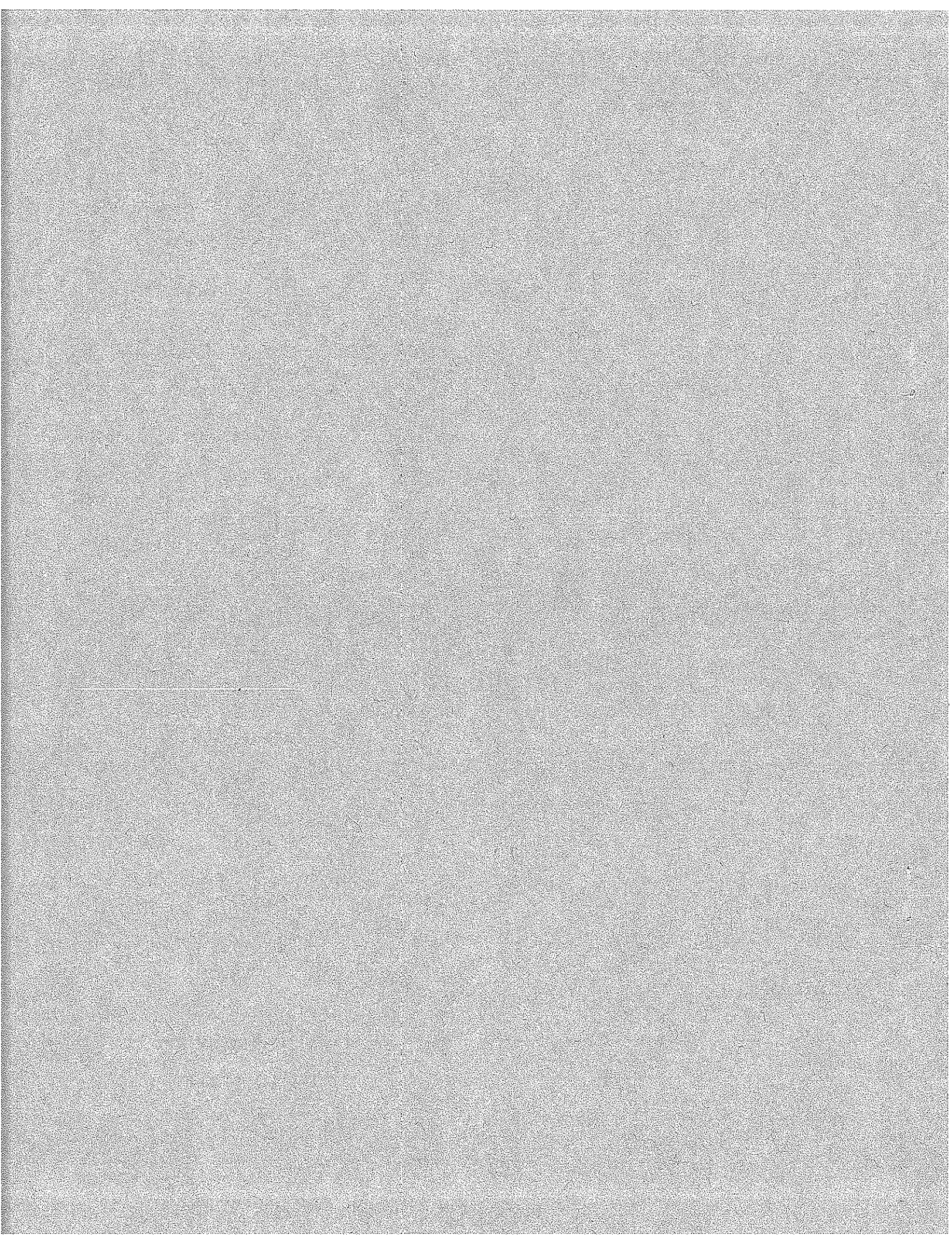
smiths

European Representative:
Graseby Medical Ltd.
WD24 4LG UK

Made in U.S.A.

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Registered Trademarks

US Patent Nos: 5,063,994; 5,097,898
P/N 45-34-005 Rev: C





Smiths Medical ASD, Inc.
Anesthesia and Safety Devices Division

160 Weymouth Street
Rockland MA 02370 USA
Tel: +1 781 878 8011
Fax: +1 781 878 8201
www.smiths-medical.com

October 1, 2004

Dear Valued Customer,

It has only been one year since the introduction of our 6-month reservoir maintenance protocol for the HOTLINE[®] Blood and Fluid Warmer. We have been working to extend this protocol to reduce HOTLINE[®] reservoir maintenance from twice a year to once a year, and to reduce the maintenance for the Level 1[®] Fast Flow Fluid Warmer, from 12 times a year to once a year*.

Smiths Medical ASD, Inc. is pleased to announce the new

ONE-YEAR MAINTENANCE PROTOCOL

for HOTLINE[®] Blood and Fluid Warmer and Level 1[®] Fast Flow Fluid Warmer

Benefits for you:

- Maintain a microbe-free environment

We use a disinfecting procedure, unlike hotplate warmers which use superficial cleaning that does not disinfect or sterilize.

- Maintenance time is reduced for the HOTLINE[®] Warmer from twice a year to once a year and for the Level 1[®] Fast Flow Fluid Warmer from 12 times a year to once a year

Using hydrogen peroxide mixing bottles will make for easier mixing, pouring and storage of the 0.3% hydrogen peroxide/distilled water solution. To find out more about the mixing bottles please contact your local sales representative or Customer Service at 800-258-5361.

- Yearly maintenance costs are reduced

The HOTLINE[®] Warmer and the Level 1[®] Fast Flow Fluid Warmer require cleaning maintenance costs only once a year, unlike hotplate warmers which may require cleaning maintenance costs up to 12 times a year.

If you would like additional information regarding the new one-year maintenance protocol for the HOTLINE[®] Blood and Fluid Warmer and/or the Level 1[®] Fast Flow Fluid Warmer, please do not hesitate to contact us at the below numbers.

Technical Support	1-800-553-8351, prompt 5
Jill Goudreau	1-800-553-8351 x7893
Poonam Viridi, Product Manager	1-800-553-8351 x7851

TECHSERV@smiths-medical.com
jill.goudreau@smiths-medical.com
poonam.viridi@smiths-medical.com

Sincerely,

Jill C. Goudreau

Associate Product Manager, Fluid Warming

*Data on file



ONE-YEAR RESERVOIR MAINTENANCE PROTOCOL

The one-year maintenance solution is a 0.3% hydrogen peroxide/distilled water solution. The below protocol should be followed annually for the Level 1* Fast Flow Fluid Warmer (H-1200, H-1025, H-1000, H-1100), as well as for the initial set up in your facility.

Level 1* Fast Flow Fluid Warmer

To prepare 0.3% hydrogen peroxide/distilled water solution for the reservoir, mix 140 mL of 3% hydrogen peroxide solution and 1,260 mL of distilled water.

1. Empty reservoir of current solution.
2. Place a container under the drain valve of the Level 1* Fast Flow Fluid Warmer.
3. Drain the re-circulating solution by turning the drain valve clockwise 90 degrees.
4. When all of the re-circulating solution has drained from the unit, close the drain valve.
5. Refill the unit with 1.4 liters of fresh 0.3% hydrogen peroxide/distilled water solution.
6. Insert a D-series disposable set (D-50/DI-50, D-60HL/DI-60HL, D-100/DI-100, D-300/DI-300) into the Level 1* Fast Flow Fluid Warmer. If you use a Level 1* Fast Flow Fluid Warmer for urological and/or gynecological procedures, insert an IR-series disposable set (IR-500, IR-600/RI-600/RI-600B, IR-700, IR-40).
7. Turn the unit on and run for a 30-minute disinfection period.
8. Switch the unit off, discard the disposable according to established hospital procedures and empty the reservoir of the re-circulating solution by turning the drain valve clockwise 90 degrees. When all of the re-circulating solution has been drained from the unit, close the drain valve.
9. Refill the reservoir with 1.4 liters of fresh 0.3% hydrogen peroxide/distilled water solution. The Level 1* Fast Flow Fluid Warmer is now ready for use.

During the 12-month period, any solution lost from the reservoir through the disposable must be topped off with the 0.3% hydrogen peroxide/distilled water solution.



ONE-YEAR RESERVOIR MAINTENANCE PROTOCOL

The one-year maintenance solution is a 0.3% hydrogen peroxide/distilled water solution. The below protocol should be followed annually for the HOTLINE® Blood and Fluid Warmer (HL-90), as well as for the initial set up in your facility.

HOTLINE® Blood and Fluid Warmer

To prepare 0.3% hydrogen peroxide/distilled water solution for the reservoir, mix 140 mL of 3% hydrogen peroxide solution and 1,260 mL of distilled water.

1. Empty solution currently in HOTLINE® Warmer reservoir.
2. Fill the reservoir with 1.4 liters of fresh 0.3% hydrogen peroxide/distilled water solution.
3. Insert a disposable set (L-70 or L-70 NI) into the HOTLINE® Warmer.
4. Turn the unit on and let the solution circulate for a 30-minute disinfection period.
5. Switch the unit off and empty the reservoir. Discard the disposable according to established hospital procedures.
6. Refill the reservoir with 1.4 liters of fresh 0.3% hydrogen peroxide/distilled water solution. The HOTLINE® Blood and Fluid Warmer is now ready for use.

During the 12-month period, any solution lost from the reservoir through the disposable must be topped off with the 0.3% hydrogen peroxide/distilled water solution.

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Anesthesia and Safety Devices Division

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RECOMMENDED ONE-YEAR MAINTENANCE CHECKLIST

Model: Level 1® Fast Flow Fluid Warmer

Ref: H-1000, H-1100, H-1025, H-1200

One-Year Reservoir Maintenance Protocol for the Level 1 Fast Flow Fluid Warmer*

A new one-year reservoir maintenance protocol was launched in 2004 for Level 1 Fast Flow Fluid Warmer. This maintenance protocol involves using a 0.3% hydrogen peroxide/distilled water solution that maintains a microbe-free environment for one year. For details on this upgraded version of our reservoir maintenance protocol, please contact your local Smiths Medical ASD, Inc. representative or contact our Technical Support Department at 1-800-553-8351.

One-Year Maintenance Tasks

All testing and maintenance should be performed by qualified personnel only.

Date of purchase: _____

Serial number: _____

Task	Date	Date	Date	Date
Change 0.3% Hydrogen Peroxide/Distilled Water Solution				
Replace O-Rings				
Clean Fan Filter				
Test Over-Temp Alarm				
Test Float Switch				
Test Disposable Interlocks				
Verify Temperature Calibration				

*The one-year maintenance protocol is in addition to the maintenance protocols listed in the Fast Flow Fluid Warmer operator's manual.

P/N 73-10-129 Rev. A



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RECOMMENDED ONE-YEAR MAINTENANCE CHECKLIST

Model: HOTLINE® Blood and Fluid Warmer

Ref: HL-90

HOTLINE Blood and Fluid Warmer One-Year Reservoir Maintenance Protocol*

A new one-year reservoir maintenance protocol was launched in 2004 for the HOTLINE Warmer reservoir. This maintenance protocol involves using a 0.3% hydrogen peroxide/distilled water solution that maintains a microbe-free environment for one year. For details on this upgraded version of our reservoir maintenance protocol, please contact your local Smiths Medical ASD, Inc. representative or contact our Technical Support Department at 1-800-553-8351.

One-Year Maintenance Tasks

All testing and maintenance should be performed by qualified personnel only.

Date of purchase: _____

Serial number: _____

Task	Date	Date	Date	Date
Change 0.3% Hydrogen Peroxide/Distilled Water Solution				
Replace O-Ring and Seals				
Lubricate O-Rings				
Test Alarm Switch				
Test Float Switch				
Test Disposable Switch				
Test Over-Temp Alarm				
Verify Temperature Calibration				

*The one-year protocol is an addition to the maintenance protocols listed in our HOTLINE® Warmer operators manual.

*The one-year reservoir maintenance protocol supercedes the 6-Month maintenance protocol.

P/N 73-10-128 Rev. A



Bivona®

LEVEL 1

INSTRUCTIONS FOR USE

HOTLINE® WARMER

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ABOUT THIS MANUAL

REFERENCES:

The HL-90 **HOTLINE**® Warmer will be referred to as **HOTLINE**®.

The L Series Fluid Warming Set will be referred to as the **HOTLINE**® Warming Set.

The distilled circulating water will be referred to as the Circ. H₂O.

MESSAGES:

Messages that are headed by "**NOTE:**" indicate information or procedures that if not followed correctly can cause improper results.

Messages that are headed by "**CAUTION:**" indicate information or procedures that if not followed correctly can cause improper results and damage to the equipment.

Messages that are headed by "**WARNING:**" indicate information or procedures that if not followed correctly can cause improper results, damage to the equipment, and serious patient harm.

INDICATIONS

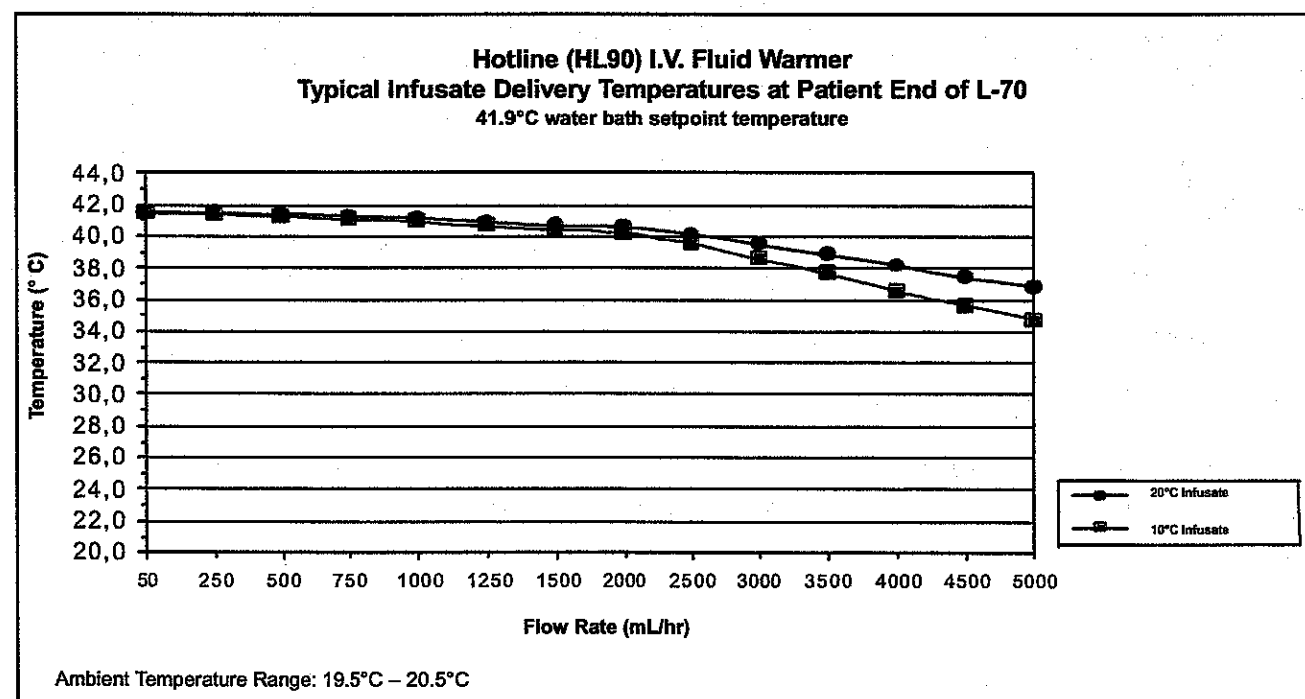
The **HOTLINE**® Warmer is designed for use with the **HOTLINE**® Warming Set to warm blood and I.V. fluids and deliver them to the patient's intravenous access site at normothermic temperatures under gravity flow conditions.

PRINCIPLES OF OPERATION

The **HOTLINE**® delivers fluids and blood at normothermic temperatures at routine, gravity flow rates. All other fluid warming systems suffer from cool-down between the warmer and the patient connection. **HOTLINE**® overcomes this problem by providing active warming of the patient line all the way to the patient connection, protecting the patient line against exposure to cold and eliminating patient line cool-down. Active warming is achieved by jacketing the sterile patient I.V. line with a layer of precisely temperature controlled circulating warm water. An 8' (2.4m) **HOTLINE**® Warming Set allows blood and intravenous fluid to be delivered to the patient at normothermic temperature at gravity flow rates to 4,500 mL per hour (83mL per minute).

The **HOTLINE**® Warmer and Warming Set are an integrated, highly effective design with unparalleled ease of use. Properly trained users can confidently and safely have the **HOTLINE**® set-up and operating within seconds.

NOTE: The **HOTLINE**® Warmer must be used only with **HOTLINE**® Fluid Warming Sets.






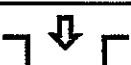


DESCRIPTION

HOTLINE® WARMER:

An on board water supply is heated to 42°C and circulated through the **HOTLINE®** Warming Set. Electronic circuitry continuously monitors the water temperature. Circulating water temperature and visual alarms are indicated on the Display Panel on the front of the unit. A green "OPERATING" or "WARMING" light illuminates on this panel when the unit is set-up and operating correctly.

DISPLAY PANEL:

Five displays provide information for safe, convenient use of the device.

SYMBOL	DISPLAY	DESCRIPTION
		Displays temperature of circulating water in degrees Celsius.
	"OPERATING" or "WARMING"	This green indicator illuminates when the power switch is "ON" and the HOTLINE Warming System has been properly installed. Indicates fluid warming is taking place.
	"DISPOSABLE"	This red indicator and pulsed audible alarm indicate the HOTLINE Warming Set is not properly installed. Fluid warming is not taking place.
	"ADD WATER"	This red indicator and pulsed audible alarm indicate additional distilled water must be added to the reservoir. Fluid warming is not taking place.
	"OVER- TEMPERATURE"	This red indicator and pulsed audible alarm indicate a malfunction of the primary temperature control system. Fluid warming is not taking place. HOTLINE should be removed from service.

HOTLINE® WARMING SET:

Single Use **HOTLINE®** Warming Sets are provided in single unit packaging with Sterile Fluid Path. The priming volume of the warming set is 17.5 mL. A plug-in fitting on the **HOTLINE®** Warming Set engages a socket in the **HOTLINE®** Warmer. This is the only connection necessary to provide the warming function. The **HOTLINE®** Warming Set is easily unplugged from the **HOTLINE®** Warmer and discarded, or it may be used to continue subsequent unwarmed infusion.

SAFETY

The **HOTLINE®** employs a safe, circulating water heating system, inherently free of "hot spots" to actively warm the patient line. The primary temperature control circuit limits the circulating water to 42°C maximum. In the unlikely event of a malfunction of this circuit, a second "watch-dog" circuit will visually and audibly alarm and stop the circulating water pump if the temperature reaches 43°C. Fluid in the **HOTLINE®** Warming Set is never exposed to any damaging or dangerous temperatures while the unit is operating.

The **HOTLINE®** is manufactured to be in compliance with UL 2601-1 (HL-90 115V) and EN 60601-1 (HL-90 230V).

CONTRAINDICATIONS:

- Not for use in warming cryo-precipitates or granulocyte suspensions.

WARNINGS:

- Failure to follow warnings may result in patient injury or death.
- The **HOTLINE®** Warming Set is a Single Use device and is not intended for resterilization.
- Sterile Fluid Path. If caps are not in place, then sterility will be compromised.
- Set-up, priming and use require aseptic technique. Follow applicable hospital policies and procedures.
- Prime the circulating water path before connecting to the intravenous administration set. This is to confirm that there is not a breach between the circulating water path and IV path. If fluid exits the patient end before connecting to intravenous administration set, remove and replace administration set.
- All air must be removed from the intravenous fluid lines before connecting to the patient. Failure to do so may result in introduction of air to the patient, which may contribute to serious patient injury or death. Monitor intravenous fluid line to make sure it is air-free.
- Do not stick the **HOTLINE®** Warming Set tubing with needles, which will compromise integrity of the patient intravenous line. If a disposable with a breached circulating water path/IV path is used, then patient illness may occur because of the fluid warmer's circulating water entering the patient's blood stream.
- Do not use **HOTLINE®** in the presence of flammable anesthetics because of the risk of fire or possibility of explosion.
- Do not use **HOTLINE®** in high energy fields such as: MRI, X-Ray, etc. **HOTLINE®** may act as a projectile in a strong magnetic field, cause image artifacts or not function as intended.

CAUTIONS:

- Federal Law (USA) restricts sale of this device to or on the order of a physician.
- Do not mount the **HOTLINE®** more than 42" (107cm) above the floor. For convenience 42" (107 cm) is indicated on the **HOTLINE®** line power cord by a black mark. Mounting the **HOTLINE®** above 42" (107cm) may result in instability of the pole and tipping.
- Do not autoclave or immerse any part of the **HOTLINE®** in liquids, which may cause damage and improper functioning.
- Insure that the **HOTLINE®** pole clamp is screwed tightly onto the IV pole. Failure to securely mount the **HOTLINE®** onto the IV pole may cause the **HOTLINE®** to slide down the IV pole.
- Not for use with pressure devices generating over 300 mmHg. Pressure greater than 300 mmHg may compromise the integrity of the **HOTLINE®** Warming Set.

NOTE: Hand pumps can generate over 1000 mmHg.

ELECTRICAL SAFETY:

POWER REQUIREMENT

Most of the current drawn by the **HOTLINE®** is for the 300-Watt immersion heater. When the device is first turned on and the digital display shows rapidly rising temperatures below 41°C, the 300-Watt heater is in a full ON condition. Beyond approximately 40°C, the proportional controller cycles the heater ON/OFF with proportionally shorter ON times as the circulating water nears the 41.5°C set point.

ELECTRICAL SAFETY TESTING:

All testing and maintenance should be performed by qualified personnel. Safety testing is to be conducted on an annual basis. This involves earth leakage and ground continuity, which must be tested according to UL 2601-1 and EN 60601-1.

NOTE: *This device is equipped with disposable sensing interlocks. A **HOTLINE®** Warming Set is required to correctly operate the device and perform leakage current testing. Do not defeat the disposable sensing interlocks or try to operate the **HOTLINE®** without a Warming Set in place.*

Earth leakage must be tested according to UL 2601-1 and EN 60601-1. Earth leakage current test should be performed with the immersion heater circuit in the full ON condition. For this reason, leakage current test should be performed on a **HOTLINE®** that has room temperature water in the water tank.

Ground continuity must be tested according to UL 2601-1 and EN 60601-1.

HOTLINE® is certified that it is in compliance with the European Communities Council Directive relating to Electromagnetic Compatibility (EMC): (89/336/EEC). Test methods and acceptance criteria as specified in EN 60601-1-2 demonstrate conformance.

STORAGE

Store in a cool dry place. Do not expose to extreme temperature. See Environmental Specifications for more details.

PREPARATION AND SET-UP

HARDWARE:

WARNING: *This unit should be tested by hospital biomedical personnel prior to placing it in service. All testing and maintenance should be performed by qualified personnel.*

Step 1: CLAMP THE HOTLINE® SECURELY TO AN I.V. POLE.

CAUTION: *Do not mount the HOTLINE® more than 42" (107cm) above the floor.* For convenience, 42" (107cm) is indicated on the HOTLINE® line cord by a black mark. Mounting the HOTLINE® above 42" (107cm) may result in instability of the pole and tipping.

CAUTION: *This unit is cooled by convection. Be sure the air vents on the bottom and the back of the unit are kept clear.*

CAUTION: Insure that HOTLINE® pole clamp is screwed tightly onto the IV pole. Failure to securely mount the HOTLINE® onto the IV pole may cause the HOTLINE® to slide down the pole.

Step 2: FILL THE WATER TANK

1. Unscrew the fillport plug on the water tank.
2. Fill the water tank with 1.4 liters of either:

- Distilled water

Or if being used as a maintenance solution, disinfect per Instructions on page 9 before filling with either:

- A 0.3% Hydrogen Peroxide / distilled water solution: mix 140 mL of 3% Hydrogen Peroxide and 1,260 mL of distilled water (this will equal 1.4L of fluid)
OR
- A 35% Isopropyl alcohol / distilled water solution: mix 700 mL of 70% Isopropyl alcohol and 700 mL of distilled water (this will equal 1.4L of fluid)

These suggested instructions are designed to be used in conjunction with established hospital procedures.

NOTE: *Use Distilled Water only. Failure to do so may cause a build-up of mineral deposits in the circulating water path which may impair heater performance.*

CAUTION: *Do not fill the HOTLINE® water tank with a HOTLINE® Warming Set in place. Failure to remove the Warming Set before the fill procedure may result in an air lock in the HOTLINE® Warmer.*

3. Replace the fillport plug.
4. Plug the HOTLINE® into the applicable outlet (115V~ or 230V~).

INSTRUCTIONS FOR USE

STEP 1: HOTLINE® WARMER SET-UP

1. Check that the water level is above the minimum level mark on the tank. Add distilled water to the tank through the fillport if required.
2. Plug into power outlet.

STEP 2: SET-UP THE HOTLINE® WARMING SET

To set up the **HOTLINE®** Warming Set you will need the following:

- **HOTLINE®** Warmer
 - **HOTLINE®** Warming Set (L - Series)
 - Intravenous fluid or blood
 - Intravenous administration set
 - Extension Set, 8" (20cm) or less in length (optional)
1. Plug the Twin-Tube Connector into the socket on the right side of the **HOTLINE®** Warmer.
 2. Activate the Power Switch on the left side of the Warmer. The green light on the display panel will illuminate and the circulating water bath temperature display will begin to increase.
 3. The circulating water path will automatically prime when the unit is turned on. Inspect the patient end of the tubing for leaks to confirm the integrity of the intravenous pathway.

STEP 3: CONNECT THE INTRAVENOUS ADMINISTRATION SET

1. Connect the I.V. fluid and the intravenous administration set to the **HOTLINE®** Warming Set.
2. Fully prime the intravenous administration set, the **HOTLINE®** Warming Set, and patient extension set (if used).
3. Connect to the patient's intravenous access site without entrapping air.

STEP 4: USE

1. The circulating water bath temperature display will reach 37°C in about 4 minutes.
2. Adjust the rate of flow using the clamp on the intravenous administration set.

NOTE: *Do not kink the disposable set tubing. Do not restrict the water circulation through the tubing.*

STEP 5: AFTER USE

1. Turn off the Power Switch on the left side of the Warmer.
2. Remove the **HOTLINE®** Warming Set.
3. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.
4. Wipe down the external surfaces of the **HOTLINE®** Warmer with mild detergent, water, and a soft cloth. For external disinfection, a 10% bleach/distilled water solution may be used.

TROUBLESHOOTING

Problem:	Check:
No power	<ul style="list-style-type: none"> • Unit plugged in? • Power switch on? • NOTE: <i>If plugged in and power switch is "ON", the green or red LEDs will glow.</i>
DISPOSABLE alarm	<ul style="list-style-type: none"> • Disposable properly installed? Push Twin-tube Connector firmly into HOTLINE® Warmer Socket.
ADD WATER alarm	<ul style="list-style-type: none"> • Add distilled water to the water tank to the MAX fill line. • CAUTION: <i>Do not fill the HOTLINE® water tank with a HOTLINE® Warming Set in place.</i>
CIRCULATING WATER BATH OVER TEMPERATURE alarm	<ul style="list-style-type: none"> • Check Warming Set for tubing kinks or other restrictions. • Check for air lock: Turn Power Switch "OFF", remove the Warming Set, gently shake HOTLINE® to dislodge air, plug in Warming Set and turn Power Switch "ON". • If there are no restrictions or air present, remove the HOTLINE® from service and return it for repair or replacement.
Hot Cabinet	<ul style="list-style-type: none"> • Blocked air vents on the bottom or the back of the unit? • NOTE: <i>Room temperature above 42°C may cause the HOTLINE® to shut down and the over temperature alarm to activate. In this unusual situation, turn the power switch off and allow the unit to cool down before returning it to service.</i>
Hard to install the Warming Set	<ul style="list-style-type: none"> • Grease O-rings in the socket as per the instructions in this manual. See "Maintenance".
Water leaks at the socket where the Warming Set plugs into the unit.	<ul style="list-style-type: none"> • Replace O-rings. Order P/N 80-04-001

MAINTENANCE

All testing and maintenance should be performed by qualified personnel.

EXTERNAL CLEANING: EVERY USE

For routine cleaning use only mild detergents, water and soft cloth.

For external disinfecting, a 10% bleach/distilled H₂O solution may be used.

CAUTION: *Do not autoclave.*

Do not use alcohol, abrasive cleaning agents, solvents or cold sterilants. These agents will cause the unit to crack.

*Do not immerse any part of the **HOTLINE®** in liquids.*

GENERAL INSPECTION: EVERY USE

Visually check the condition of the unit. Remove from service any unit which shows physical damage or one in which the **HOTLINE®** Warming Set does not install easily.

CHANGE DISTILLED WATER SOLUTION: EVERY 30 DAYS

1. Unplug the unit before servicing.
2. Remove the fillport plug from the water tank.
3. Invert the unit over a sink or suitable container to remove the water from the unit. Rinse tank with distilled H₂O twice before returning to use.
4. Re-attach to I.V. pole.
5. Refill the unit with 1.4 Liters of distilled water solution. Refer to Set-up and/or Disinfection instructions for filling options.

NOTE: *Use Distilled Water only. Failure to do so may cause a build-up of mineral deposits in the circulating water path which may impair heater performance.*

CAUTION: *Do not fill the **HOTLINE®** water tank with a **HOTLINE®** Warming Set or a **TEMP CHECK** in place. Failure to remove the Warming Set before the fill procedure may result in an air lock in the **HOTLINE®** Warmer.*

6. Replace the fillport plug.

LUBRICATE O-RING SEALS: EVERY 30 DAYS

Using a cotton swab apply a small amount of silicone grease to the O-rings. Silicone grease is available from LEVEL 1: Silicone Grease P/N 80-04-002

REPLACE O-RING SEALS: EVERY 12 MONTHS

1. Remove the socket head screws with a 1/8" (.31cm) hex wrench.
 2. Remove the disposable interface block, being careful not to damage the micro-switch lever.
 3. Remove the old O-rings and clean the sockets with a cotton swab.
 4. Apply silicone grease to 2 new O-rings and install into the sockets.
 5. Reassemble in reverse order being careful not to damage the micro-switch lever.
- O-Ring Kit: P/N 80-04-001

DISINFECTION

To disinfect the circulating water bath, the following procedure may be employed:

1. Unplug the unit before servicing.
 2. Remove the fillport cap.
 3. Empty all water from the reservoir tank.
 4. Fill the water tank with 1.4 liters of either:
- A 0.3% Hydrogen Peroxide / distilled water solution: mix 140 mL of 3% Hydrogen Peroxide and 1,260 mL of distilled water (this will equal 1.4L of fluid)
 - OR
 - A 35% Isopropyl alcohol / distilled water solution: mix 700 mL of 70% Isopropyl alcohol and 700 mL of distilled water (this will equal 1.4L of fluid)

These suggested instructions are designed to be used in conjunction with established hospital procedures.

NOTE: *Use Distilled Water only. Failure to do so may cause a build-up of mineral deposits in the circulating water path which may impair heater performance.*

CAUTION: *Do not fill the **HOTLINE®** water tank with a **HOTLINE®** Warming Set in place. Failure to remove the Warming Set before the fill procedure may result in an air lock in the **HOTLINE®** Warmer.*

5. Insert a Warming Set into the machine.
6. Turn the unit on and let the solution circulate for 30 minutes.
7. Switch the unit off and empty.

8. Thoroughly rinse the unit with distilled water or equivalent.
9. Refill the reservoir tank with 1.4 liters of distilled water solution. Refer to Set-up instructions for filling options.
10. These suggested instructions are designed to be used in conjunction with established hospital procedures.

TESTING

All testing and maintenance should be performed by qualified personnel.

CAUTION: *If any alarm conditions are not met remove the unit from service.*

NOTE: *Alarm testing requires a **HOTLINE®** Warming Set to be installed and the unit operating.*

Alarm Test Switch: The **HOTLINE®** is equipped with two membrane switches on the side label. Pressing the Alarm Test Switch activates all alarm conditions. Pressing and holding the Over Temp Test Switch activates the over temp alarm condition.

To Test the **HOTLINE®** Alarm Circuitry:

1. Press the Alarm Test Switch.
2. Observe that the green LED goes out.
3. The three red LED's will light.
4. The audible alarm will sound.
5. Water will stop circulating. (This can be checked by observing the return port inside the water tank.)

To test the Circulating Water Bath Over Temperature Alarm:

1. The unit should be running at an operating temperature of approximately 41°C to 42°C.
2. Press and hold the Over Temp Test Switch.
3. The Circulating Water Bath Over Temperature Alarm will activate at 43°C.
4. Observe that the green LED goes out.
5. The Circulating Water Bath red LED will light.
6. The audible alarm will sound.
7. Water will stop circulating. (This can be checked by observing the return port inside the water tank.)

Add Water Alarm: The **HOTLINE®** is equipped with a float switch, which senses the water level in the water tank. When the water is too low, the ADD WATER Alarm will activate.

To test the Add Water Alarm circuit:

1. Unscrew the fillport plug on the water tank.
2. Gently depress the float switch. (This action will simulate the low water condition.)
NOTE: *Use a non-metal tool to depress the float switch because the float switch contains a magnet.*
3. Observe that the green LED goes out.
4. The red LED will light.
5. The audible alarm will sound.
6. Water will stop circulating. (This can be checked by observing the return port inside the water tank.)

Disposable Alarm: An interlock switch located in the Disposable Interface Block senses a properly installed Warming Set. When the switch does not sense a Warming Set the DISPOSABLE alarm will activate.

To test the Disposable Alarm circuit:

1. Slowly remove the **HOTLINE®** Warming Set from the **HOTLINE®**.
2. Observe that the green LED goes out.
3. The red LED will light.
4. The audible alarm will sound.
5. Water will stop circulating. (This can be checked by observing the return port inside the water tank.)

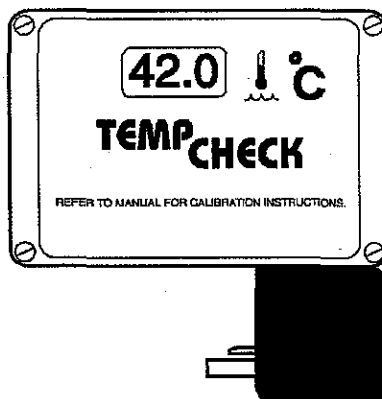
In any alarm condition the pump should not be running. A small amount of water dripping from the disconnection is normal and should stop in a few seconds.

TEMPERATURE VERIFICATION

All testing and maintenance should be performed by qualified personnel.

Displayed Circulating Water Temperature: Should be verified using a Level 1 **TEMP CHECK** Thermometer (HLTA-40). Other methods of temperature verification may be inaccurate. Units can be returned for temperature verification.

Principles of Operation: The Circ. H₂O is pumped from the water tank through the heater. The Circ. H₂O then passes the **HOTLINE**® thermistor, assembled within the heater on the output side, and then through the **TEMP CHECK**. After this point the Circ. H₂O temperature begins to drop due to the effect of ambient temperature on the disposable set. **The temperature of the water tank is typically 0.5°C to 2.0°C lower than the temperature from the heater.** Verifying the operating temperature of the Circ. H₂O by temperature readings in the water tank will be inaccurate. The **TEMP CHECK** senses the highest temperature of the Circ. H₂O bath.



CAUTION: Refer to the **TEMP CHECK HLTA-40 Thermometer Operator's Manual** for complete Temperature Verification and Calibration Instructions.

SET-UP:

To set up the **TEMP CHECK** you will need the following:

- **TEMP CHECK** (HLTA-40)
- **HOTLINE**® Warmer
- **HOTLINE**® Warming Set

1. Plug the **HOTLINE**® Warmer into power outlet.
2. Place the **TEMP CHECK** onto the top right corner of the **HOTLINE**® Warmer and plug it into the socket on the right side of **HOTLINE**®.
3. Plug the Twin-Tube Connector on the **HOTLINE**® Warming Set onto the socket on the right side of the **TEMP CHECK**.
4. Remove the black label from the auxiliary outlet on the back of the **HOTLINE**® and plug in the **TEMP CHECK** power cord.

CAUTION: The auxiliary outlet is for use only with LEVEL 1 accessories.

5. Activate the Power Switch on the left side of **HOTLINE**®. Allow 15 minutes for the temperature to stabilize.
6. If the **TEMP CHECK** display indicates a temperature between 41°C and 42°C, and the **HOTLINE**® display equals the **TEMP CHECK** display, water bath verification is complete. Refer to the **TEMP CHECK** Manual for OVERTEMP ALARM verification.
7. If the **TEMP CHECK** display does not indicate a temperature between 41°C and 42°C, refer to the **TEMP CHECK** Manual for calibration instructions.

RECOMMENDED MAINTENANCE CHECK LIST

MODEL: HOTLINE® FLUID WARMER

REF: HL-90

All testing and maintenance should be performed by qualified personnel.

Write your date of purchase here _____

Write your serial number here _____

30-day maintenance tasks

Change Distilled Water Solution											
Grease O-ring Seals											
Test Alarm Switch											

12 months maintenance tasks

Test Alarm Switch											
Test Float Switch											
Test Disposable Switch											
Test Over Temperature Alarm											
Replace O-ring seals											
Verify Temperature/ Calibrate											

You may photo copy this form for your record keeping.

Notes:

LIMITED WARRANTY SECTION

LEVEL 1 FLUID WARMER HOTLINE® FLUID WARMER

This **HOTLINE®** Warmer is warranted by LEVEL 1 to be free from defects in material or workmanship for a period of 1 year (12 months) from the date of shipment to the customer. If the customer finds any **HOTLINE®** Warmer device to have such defects during this period, it should be returned to the address given below. At LEVEL 1's option, the product will either be repaired or replaced by a new machine and returned to the Customer. Provided LEVEL 1 confirms that there were defects in the **HOTLINE®** machine, LEVEL 1 will also refund the Customer's reasonable cost of returning the machine for repair.

This Warranty will not apply in respect of any **HOTLINE®** product which does not have its original Serial Number plate intact. Nor will this Warranty apply to any damage or defect caused by misuse of the product; by careless or deliberate mistreatment of the product; or by any impact to the product.

In no event will LEVEL 1 or its distributors be liable for consequential or economic loss incurred by the Customer.

The liability of LEVEL 1 and its distributors for any defect in the **HOTLINE®** product will be limited to the invoice value of the product.

This Warranty does not affect any warranty or guarantee to which the Customer is irrevocably entitled by virtue of any applicable law. With that proviso, this Warranty replaces all other express or implied warranties, representations or indemnities to which the Customer may otherwise be entitled by virtue of any law, trade practice or otherwise.

SERVICE

CAUTION: ALL SERVICE MUST BE PERFORMED AND/OR AUTHORIZED BY LEVEL 1 OR A LEVEL 1 DISTRIBUTOR. SERVICE BY OTHERS VOIDS THE WARRANTY AND TRANSFERS LIABILITY FOR MALFUNCTIONS OF THE DEVICE TO THE SERVICING ORGANIZATION.

WARRANTY SERVICE

Units received for repair, which have not been obviously abused or impact damage and are still under Warranty will be promptly repaired and returned at no charge. See the limited warranty section of this manual. A no-charge purchase order is requested for tracking.

NON-WARRANTY WORK

Units received which have suffered obvious abuse or impact damage and units no longer under Warranty will be promptly inspected and a verbal estimate of repair cost will be given to you. A purchase order will be required from the hospital consistent with the verbal estimate. A written estimate will be provided upon request.

Be sure that ALL water is drained from the **HOTLINE®** before packing the **HOTLINE®** for shipment.

NOTE: *HOTLINE® must be cleaned and disinfected for repair shipment or it will be immediately returned as received.*

FOR SERVICE, CONTACT YOUR LEVEL 1 DISTRIBUTOR OR THE LEVEL 1 TECHNICAL SERVICE DEPARTMENT AT:

LEVEL 1 Technical Service Department:
Phone: 1-800-553-8351
E-mail: techserv@simslevel1.com

SPECIFICATIONS

If the **HOTLINE®** should encounter any electrical interference, either receiving or transmitting, move the **HOTLINE®** away from the device in question. Plug the **HOTLINE®** into a separate electrical circuit. If problem continues, notify LEVEL 1 or your LEVEL 1 Authorized Representative for assistance.

PHYSICAL SPECIFICATIONS:

Electrical Classification: Class 1 Equipment, Type CF

This equipment is not suitable for use in the presence of flammable anesthetics mixture with air or oxygen or with nitrous oxide.

Height	9.5 inches	(24.1 cm)
Length	8.3 inches	(21 cm)
Width	7.0 inches	(17.8 cm)
Weight dry	7.6 lbs.	(3.5 Kg)
Weight wet	11.0 lbs.	(5.0 Kg)
Weight, Shipping	7.95 lbs.	(3.6 Kg)

ELECTRICAL SPECIFICATIONS:

Input Voltage	115V~	230V~
Operating Frequency	50-60 Hz	50-60 Hz
Operating Current	3.0A	1.5A
Leakage Current	Earth Leakage Current <500 µA	Earth Leakage Current <500 µA
Power Cord	0.75 mm x 3.6 m <HAR>	0.75 mm x 3.6 m <HAR>

OPERATING SPECIFICATIONS:

Source Temperature	41.5°C ± 0.5°C
Max. Height on I.V. Pole	42 inches (107 cm)

This equipment was tested for compliance to UL 544 and EN 60601-1.

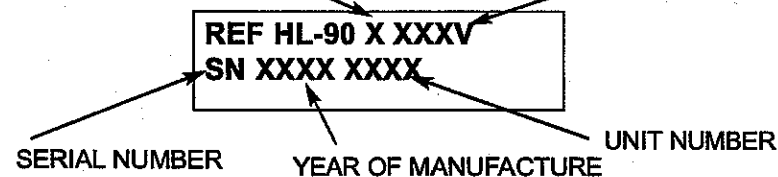
ENVIRONMENTAL SPECIFICATIONS:

	Temperature
Operation	10°C - 45°C
Transport	-20°C - 70°C
Storage	-20°C - 70°C

SERIAL NUMBER

COUNTRY/LANGUAGE CODE

REFERENCE NUMBER


















ELECTRICAL SCHEMATICS AND PARTS LIST

Electrical schematic and Parts List are available from LEVEL 1 Technical Service Department or your LEVEL 1 distributor. They are for reference only and are not intended for user service. Any service performed on this unit not authorized by LEVEL 1 or a LEVEL 1 distributor will void the warranty and transfer liability for any malfunction to the servicing organization. LEVEL 1 reserves the right to make changes, without further notice, to any products herein to improve reliability, function, or design.

LEVEL 1 Technical Service Department:

Phone: 1-781-878-8011

E-mail: techserv@simslevel1.com

CAUTION! READ INSTRUCTIONS BEFORE USE	
DEGREES CELSIUS	
CIRCULATING WATER BATH TEMPERATURE	
OPERATING / WARMING	
ADD WATER	
OVERTEMPERATURE	
ALARM TEST BUTTON	
OVERTEMPERATURE ALARM TEST BUTTON	
WATER LEVEL, MAXIMUM AND MINIMUM	
ALTERNATING CURRENT	
TYPE BF APPLIED PART	
PROTECTED AGAINST DRIPPING WATER	IPX 1
ELECTRICAL SHOCK HAZARD	
DATE OF MANUFACTURE	
STERILE FLUID PATH, STERILIZED BY ETHYLENE OXIDE	
SINGLE USE ONLY	
LATEX FREE	LATEX FREE

LOT	LOT
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ON FOR A PART OF THE EQUIPMENT	I
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